



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2011-F-0765]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Acacia (Gum Arabic)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to provide for the expanded safe use of acacia (gum arabic) in foods. This action is in response to a petition filed by Nexira.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section IX of this document for information on filing objections. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Director of the Office of the Federal Register approves the incorporation by reference of a certain publication listed in the rule as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA-2011-F-0765, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for

submitting comments.

### Written Submissions

Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-F-0765 for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1309.

SUPPLEMENTARY INFORMATION:

### I. Background

In a notice published in the Federal Register on December 20, 2011 (76 FR 78866), we announced that Nexira, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West,

Washington, DC 20001 (petitioner) had filed a food additive petition (FAP 1A4784). The petition proposed to amend the food additive regulations in § 172.780, Acacia (gum arabic) (21 CFR 172.780) to provide for the expanded safe use of acacia (gum arabic) in food. Specifically, the petition proposed to list the use of acacia in § 172.780 as a source of dietary fiber in the existing food categories listed in § 184.1330(c) (21 CFR 184.1330(c)), excluding meat, poultry, and foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341), and as a source of dietary fiber and as an emulsifier and emulsifier salt, flavoring agent and adjuvant, formulation aid, processing aid, stabilizer and thickener, surface-finishing agent, and texturizer in four additional food categories (i.e., breakfast cereals, certain baked products, grain-based bars, and soups). The petitioner subsequently clarified that it only proposed to list the use of acacia in soups and soup mixes that are not subject to regulation by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act or the Poultry Products Inspection Act.

Under 21 CFR 171.1(c), paragraph H, either a claim of categorical exclusion under 21 CFR 25.30 or § 25.32 (21 CFR 25.32) or an environmental assessment under 21 CFR 25.40 must be submitted in a food additive petition. A claim of categorical exclusion under § 25.32(k), which applies to substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food, was initially submitted with the petition. We reviewed the claim of categorical exclusion submitted by the petitioner and stated in the original filing notice (76 FR 78866) our determination that, under § 25.32(k), the proposed action was of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment

nor an environmental impact statement is required. However, upon further review of the petition, we decided that the food additive may replace macronutrients in food and, therefore, the categorical exclusion in § 25.32(k) was not applicable for the proposed action. Accordingly, in an amended filing notice published in the Federal Register of September 4, 2012 (77 FR 53801), we announced that the petitioner had submitted an environmental assessment for the petition in lieu of the claim of categorical exclusion, and that we would review the potential environmental impact of the petition. We placed the environmental assessment on display in the Division of Dockets Management for public review and comment.

## II. Introduction

### A. Identity

Acacia is the dried gummy exudate from the stems and branches of trees of various species of the genus Acacia, family Leguminosae. The precise molecular structure of acacia is not known, but it is generally depicted as a group of compacted polysaccharide bundles individually linked to a linear proteinaceous core. The polysaccharide is composed of the following: L-arabinose, D-galactose, L-rhamnose, and D-glucuronic acid and its 4-O methyl derivative. The composition of acacia, with respect to the proportion of sugars and to the amino acids comprising the proteins, varies depending on the species of Acacia used to produce the gum.

### B. Regulated Food Uses

In the Federal Register of September 23, 1974 (39 FR 34203), we published a proposed rule to affirm that the use of acacia as a direct human food ingredient is generally recognized as safe (GRAS), with specific limitations. In the Federal Register of December 7, 1976 (41 FR

53608), we issued a final rule based on this proposal, amending the regulations in then 21 CFR part 121 to affirm that acacia as a direct human food ingredient is GRAS with specific limitations. In the Federal Register of March 15, 1977 (42 FR 14302 at 14653), acacia was redesignated from § 121.104(g)(19) to part 184 by adding § 184.1330 Acacia (gum arabic). To ensure that acacia is not added to the U.S. food supply at levels that could raise safety concerns, we affirmed acacia as GRAS with specific limitations as listed in § 184.1330.

Under § 184.1330, acacia is affirmed as GRAS for use in various specific food categories at levels ranging from 1.3 to 85.0 percent. Use of acacia in all other food categories was limited to not more than 1.0 percent. Under § 184.1(b)(2) (21 CFR 184.1(b)(2)), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use. Any addition of acacia to food beyond those limitations set out in § 184.1330 requires either a food additive regulation or an amendment of § 184.1330. Consistent with § 184.1(b)(2), a food additive petition (FAP 1A4730) was filed in the Federal Register on February 13, 2003 (68 FR 7381) to amend the food additive regulations in part 172 (21 CFR part 172) to provide for the safe use of acacia as a thickener, emulsifier, or stabilizer in alcoholic beverages at a use level not to exceed 20 percent in the final beverage. In response to this petition, we issued a final rule in the Federal Register of February 17, 2005 (70 FR 8032), that added § 172.780 to provide for this use.

### III. Evaluation of Safety

Under the general safety standard in section 409 of the FD&C Act (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. Our food additive regulations

(21 CFR 170.3(i)) define “safe” as “a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.” To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the additive, the additive's toxicological data, and other available relevant information (such as published literature).

#### A. Proposed Uses, Exposure, and Specifications

The petitioner proposes to use acacia as a source of dietary fiber in those food categories and at the use levels listed in § 184.1330(c), excluding meat and poultry and foods for which standards of identity have been issued under section 401 of the FD&C Act. The petitioner also proposes for acacia to be used in several new food categories as described in table 1.<sup>1</sup> We evaluated the exposure to acacia based on 2009 poundage data obtained from the October 2010 Chemical Economics Handbook report on hydrocolloid usage in the United States (Acacia can be classified as a hydrocolloid, which are substances that form a gel with water and are often used as thickeners, stabilizers, or emulsifiers in food applications.) We calculated the per capita exposure of acacia to be 127 milligrams per person per day. Because acacia may be used in a wide variety of foods, the entire U.S. population could consume at least one of the foods containing acacia. Therefore, the use of a per capita exposure assessment is appropriate, as it represents the entire U.S. population (Ref. 1).

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<sup>1</sup> During our evaluation of this petition, we consulted with the Food Safety and Inspection Service (FSIS) of the USDA, consistent with 21 CFR 171.1(n) and with a memorandum of understanding (MOU) between the two Agencies for reviewing the safety of substances used in the production of meat and poultry products. Under the MOU, FDA is responsible for reviewing an ingredient's safety, and USDA/FSIS is responsible for evaluating suitability. (MOU 225-00-2000; see also 65 FR 51758 at 51759, August 25, 2000). However, during our consultation with FSIS, the petitioner clarified that it did not propose for acacia to be used in meat or poultry

Table 1.-- Proposed Uses of Acacia That Are Beyond Those Regulated Under § 184.1330(c)

Food Category	Maximum Use Level	Intended Use
Breakfast cereals	6%	Source of dietary fiber; emulsifier and emulsifier salt; flavoring agent and adjuvant; formulation aid; processing aid; stabilizer and thickener; surface-finishing agent; texturizer
Cakes, brownies, pastries, biscuits, muffins, and cookies	3%	Same as above
Grain-based bars (e.g., breakfast and snack bars, granola, rice cereal bars)	35%	Same as above
Soups and soup mixes that are not subject to USDA regulation under the Federal Meat Inspection Act or the Poultry Products Inspection Act	2.5%	Same as above

The current regulation for the use of acacia as a thickener, emulsifier, or stabilizer in alcoholic beverages (§ 172.780) indicates that the additive must meet the specifications in the Food Chemicals Codex, 7th Edition (FCC 7). The most current FCC is the 8th Edition (FCC 8) and given that the specifications for acacia in FCC 8 are identical to those in FCC 7, we are amending § 172.780 by adopting the specifications for acacia in FCC 8 in place of FCC 7.

Additionally, on our own initiative, we are amending § 172.780(b) to update the address at which copies of FCC 8 may be examined. The existing regulation refers to an FDA address at “5100 Paint Branch Pkwy., College Park, MD 20740.” However, in 2013, we consolidated our

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products, including soups and soup mixes containing meat or poultry products that are subject to regulation by USDA under the Federal Meat Inspection Act or the Poultry Products Inspection Act.

library holdings at our main library at 10903 New Hampshire Ave., Bldg. 2, 3d Floor, Silver Spring, MD 20993. Therefore, we are amending § 172.780(b) to reflect the current FDA address at which copies of FCC 8 may be examined.

### B. Safety Assessment

To support the safety of the proposed expanded use of acacia, the petitioner referenced toxicological studies and other relevant information previously reviewed by FDA (70 FR 8032).

The petitioner referenced data from a 1973 report on acacia by the Select Committee on GRAS Substances; a 1982 National Toxicology Program report on 2-year carcinogenicity feeding studies; literature searches performed in 1983, 1987, 1988, and 1992; and a 1990 evaluation of acacia by the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA).

Of the publications submitted by the petitioner, only two papers relevant to the safety assessment of acacia had not been previously reviewed by FDA. One publication was an extensive review of the scientific literature available before 2004 and focused on the general safety and allergenicity of acacia as used in cosmetic products. The review concluded that the available safety data for acacia was sufficient to ensure its safe use in cosmetics. The other publication evaluated the digestive tolerance of acacia in humans and its possible role as a prebiotic fiber. The publication claimed high doses of acacia (>50 grams per day (g/d)) are generally well tolerated based on reports of only mild physiologic responses. We reviewed both publications and concur with the conclusions (Ref. 2).

The petitioner also presented a literature review on acacia's potential as an allergen. We had previously reviewed the allergenicity literature through 1992 and concluded there was no



strong evidence that acacia is allergenic in food. In reviewing the current petition, we conducted another search of literature spanning from 1992 through 2012. This recent search of the literature did not find any published articles directly addressing the allergenicity or toxicity of acacia that were not included in the petitioner's submission, nor did this search reveal any new toxicological issues pertaining to acacia<sup>2</sup> (Ref. 2).

In our safety evaluations, we have chosen not to establish an acceptable daily intake (ADI) for acacia due to convincing evidence that acacia is non-carcinogenic and poorly absorbed, and that mild physiologic responses were reported in humans only when acacia was ingested at high doses (> 50 g/d) (Ref. 2). Furthermore, JECFA has confirmed a "not specified" ADI for acacia when it is used in accordance with good manufacturing practices.

Based on our review of the safety data and estimated dietary exposure to acacia from current and proposed food uses, we conclude that the proposed expanded use of acacia in foods is safe.

#### IV. Labeling

Under section 403(a) of the FD&C Act (21 U.S.C. 343), a food is misbranded if its labeling is false or misleading in any particular. Section 403(q)(1)(D) of the FD&C Act specifies that certain nutrients and their amounts, including dietary fiber, must be included on the label or in labeling. Similarly, section 403(r) of the FD&C Act lays out the statutory framework for the use of labeling claims that characterize the level of a nutrient in a food (e.g., "high in

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<sup>2</sup> In March 2011, we received a report of a food product containing acacia that tested positive for peanut protein. After ruling out the possibility of cross-contamination in the food production process, FDA investigations concluded that no peanut protein was present and that the positive findings were probably due to the presence of cross-reactive proteins. Although we do not view this as a food safety issue, the possibility for false positives may indicate a problem with the current analytical tests used to monitor allergens in acacia-containing foods.

fiber”) or that characterize the relationship of a nutrient to a disease or health-related condition. The petitioner cited reports and published studies to support the recognition of acacia as a source of dietary fiber. We concur that acacia supplies dietary fiber. In accordance with 21 CFR 101.9(g)(2), for food labeling compliance purposes, appropriate methods cited in Official Methods of Analysis of the AOAC International, 15th edition (e.g., AOAC 985.29) would be used for measuring the amount of dietary fiber in a food. Furthermore, if products containing acacia bear any health and/or nutrient content claims on the label or in labeling, such claims must be in compliance with current labeling regulations.

#### V. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the proposed uses of acacia in food are safe. Therefore, we are amending the regulations in part 172 as set forth in this document.

#### VI. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

#### VII. Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. Our finding of no significant impact and the

evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

#### VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### IX. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## X. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)). Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (ll)(4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

## XI. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Memorandum from D. Doell, Chemistry Review Team, CFSAN, FDA, to E. Anderson, Regulatory Review Team II, CFSAN, FDA, November 20, 2012.
2. Memorandum from T. Thurmond, Toxicology Review Team, CFSAN, FDA, to E. Anderson, Regulatory Team II, CFSAN, FDA, January 17, 2013.

#### List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

#### PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. In § 172.780, revise paragraphs (b) and (c) to read as follows:

§ 172.780 Acacia (gum arabic).

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(b) The ingredient meets the specifications of the Food Chemicals Codex, 8th ed. (2012), p. 516, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, 3d

Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(c) The ingredient is used in food in accordance with good manufacturing practices under the following conditions:

#### MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages, alcoholic	20.0	Thickener, emulsifier, or stabilizer
Breakfast cereals, § 170.3(n)(4) of this chapter	6.0	Dietary fiber; emulsifier and emulsifier salt; flavoring agent and adjuvant; formulation aid; processing aid; stabilizer and thickener; surface-finishing agent; texturizer
Cakes, brownies, pastries, biscuits, muffins, and cookies	3.0	Do.
Grain-based bars (e.g., breakfast bars, granola bars, rice cereal bars)	35.0	Do.
Soups and soup mixes, § 170.3(n)(40) of this chapter, except for soups and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act	2.5	Do.
Food categories listed in § 184.1330 of this chapter, except for meat, poultry, and foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act preclude the use of acacia	Levels prescribed in § 184.1330 of this chapter	Dietary fiber

Dated: December 2, 2013.

Susan M. Bernard,

Director,

Office of Regulations, Policy and Social Sciences,

Center for Food Safety and Applied Nutrition.

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